

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

DOROTHY WESSEL
10346 Scaggsville Road
Laurel, Maryland 20723,

BESSIE RODRIGUEZ and
JOHNNY RODRIGUEZ
722 West Amber Street
San Antonio, Texas 78221,

CANDICE KRUSZKA and
ALLEN KRUSZKA
116 South 5th Street, Box 99
Thornton, Iowa 50479,

LAURIE LAMBERTSON and
MICHAEL LAMBERTSON
24 Mullen Road
Wayne, Maine 04824,

CARMELA GERSHONOWITZ
2715 Sheila Court
East Meadow, New York 11554,

MARY ANN BERRY and
ROBERT BERRY
300 Bullard Drive
Elk City, Oklahoma 73644,

JOHN WARCHOL and
MARTHA WARCHOL
909 Reno Street
Rochester, Pennsylvania 15074,

JOAN HAWKINS
728 Briarwood Road
Hermitage, Pennsylvania 16148,

Case No. _____

JURY DEMANDED

BARBARA VENNE and
GARY VENNE
1924 Betty Jane Court
North Saint Paul, Minnesota 55109,

MARCIA COMPTON and
LUTHER COMPTON
7930 Walking Horse Circle,
Apartment 1309
Germantown, Tennessee 38138,

TED WILCOXEN, INDIVIDUALLY
AND AS ADMINISTRATOR OF
THE ESTATE OF SANDRA
WILCOXEN,
1624 White Hill Road
Stuarts Draft, Virginia 24477,

MARIE CLARK
2424 Gold Canyon Road,
Apartment 1816
San Antonio, Texas 78259,

JOSEPH CAMPESI
7247 Mill Pond Circle
Naples, Florida 34109,

ROBIN MUELLER
3809 Branch Hollow Circle
Carrolton, Texas 75207,

PLAINTIFFS,

v.

APP PHARMACEUTICALS, LLC
1501 East Woodfield Road
Suite 300 East
Schaumburg, Illinois 60173,

BEDFORD LABORATORIES
300 Northfield Road
Bedford, Ohio 44146,

HOSPIRA, INC.
275 North Field Drive
Lake Forest, Illinois 60045,

TEVA PARENTERAL MEDICINES,
INC.
19 Hughes
Irvine, California 92618,

SANDOZ, INC.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540,

DEFENDANTS.

COMPLAINT AND JURY DEMAND

NOW COME plaintiffs Dorothy Wessel, Bessie Rodriguez, Johnny Rodriguez, Candice Kruszka, Allen Kruszka, Laurie Lambertson, Michael Lambertson, Carmela Gershonowitz, Mary Ann Berry, Robert Berry, John Warchol, Martha Warchol, Joan Hawkins, Barbara Venne, Gary Venne, Marcia Compton, Luther Compton, Ted Wilcoxon, individually and as the administrator of

the estate of Sandra Wilcoxon, Marie Clark, Joseph Campese and Robin Muller (collectively “Plaintiffs”), by and through counsel, and hereby sue the defendants, APP Pharmaceuticals, Inc. (“APP”), Bedford Laboratories (“Bedford”), Hospira, Inc. (“Hospira”), Teva Parenteral Medicines, Inc. (“Teva”), and Sandoz, Inc. (“Sandoz”) (collectively “Defendants”), and for their cause of action state:

I. INTRODUCTION

1. The bisphosphonate drugs Aredia® and Zometa®, each produced and marketed by non-party Novartis Pharmaceuticals Corporation (“Novartis” or “NPC”) and other related NPC entities, each cause and precipitate osteonecrosis of the jaw, mandible or maxilla bone among patients taking those drugs. Generic Aredia (pamidronate) is produced and marketed by APP, Bedford, Hospira, Teva, and Sandoz. Osteonecrosis is bone death of an area of the bone. Osteonecrosis of the jaw is a permanently disfiguring and extremely painful condition, and can result in the complete loss of the patient’s jaw bone. Plaintiffs in this action were infused with Aredia® and/or generic Aredia (pamidronate) and have suffered osteonecrosis of the jaw bone.

II. PARTIES

A. PLAINTIFFS

2. Plaintiff Dorothy Wessel is a citizen and resident of the State of

Maryland, residing in Laurel, Maryland.

3. Plaintiff Bessie Rodriguez is a citizen and resident of the State of Texas, residing in San Antonio, Texas.

4. Plaintiff Johnny Rodriguez is the husband of Bessie Rodriguez. He resides with his wife and is a citizen and resident of the State of Massachusetts, residing in North Attleboro, Massachusetts.

5. Plaintiff Candice Kruszka is a citizen and resident of the State of Iowa, residing in Thornton, Iowa.

6. Plaintiff Allen Kruszka is the husband of Candice Kruszka. He resides with his wife and is a citizen and resident of the State of Iowa, residing in Thornton, Iowa.

7. Plaintiff Laurie Lambertson is a citizen and resident of the State of Maine, residing in Wayne, Maine.

8. Plaintiff Michael Lambertson is the husband of Laurie Lambertson. He resides with his wife and is a citizen and resident of the State of Maine, residing in Wayne, Maine.

9. Plaintiff Carmela Gershonowitz is a citizen and resident of the State of New York, residing in East Meadow, New York.

10. Plaintiff Mary Ann Berry is a citizen and resident of the State of Oklahoma, residing in Elk City, Oklahoma.

11. Plaintiff Robert Berry is the husband of Mary Ann Berry. He resides with his wife and is a citizen and resident of the State of Oklahoma, residing in Elk City, Oklahoma.

12. Plaintiff John Warchol is a citizen and resident of the State of Pennsylvania, residing in Rochester, Pennsylvania.

13. Plaintiff Martha Warchol is the wife of John Warchol. She resides with her husband and is a citizen and resident of the State of Pennsylvania, residing in Rochester, Pennsylvania.

14. Plaintiff Joan Hawkins is a citizen and resident of the State of Pennsylvania, residing in Hermitage, Pennsylvania.

15. Plaintiff Barbara Venne is a citizen and resident of the State of Minnesota, residing in North Saint Paul, Minnesota.

16. Plaintiff Gary Venne is the husband of Barbara Venne. He resides with his wife and is a citizen and resident of the State of Minnesota, residing in North Saint Paul, Minnesota.

17. Plaintiff Marcia Compton is a citizen and resident of the State of Tennessee, residing in Germantown, Tennessee.

18. Plaintiff Luther Compton is the husband of Marcia Compton. He resides with his wife and is a citizen and resident of the State of Tennessee, residing in Germantown, Tennessee.

19. Plaintiff Ted Wilcoxon was the husband of the late Sandra Wilcoxon. He is a citizen and resident of the State of Virginia, residing in Stuart's Draft, Virginia. Ted Wilcoxon is suing on his behalf, and as administrator of the estate of Sandra Wilcoxon.

20. Plaintiff Marie Clark is a citizen and resident of the State of Texas, residing in San Antonio, Texas.

21. Plaintiff Joseph Campese is a citizen and resident of the State of Florida, residing in Naples, Florida.

22. Plaintiff Robin Mueller is a citizen and resident of the State of Texas, residing in Carrollton, Texas.

23. Dorothy Wessel, Bessie Rodriguez, Candice Kruszka, Laurie Lambertson, Carmela Gershonowitz, Mary Ann Berry, John Warchol, Joan Hawkins, Barbara Venne, Marcia Compton, Sandra Wilcoxon, Marie Clark, Joseph Campese, and Robin Mueller (collectively the "Bisphosphonate Consumers") were prescribed, purchased, and infused with Aredia® and/or generic Aredia

(pamidronate) and as a result thereof suffered severe osteonecrosis of the jaw, including pain, infection, and disfigurement. As is the case with all patients suffering from this condition, the Bisphosphonate Consumers are at risk for needing invasive procedures or surgeries in the future should the condition require it or should it deteriorate further.

24. In addition, osteonecrosis of the jaw is a potentially fatal disease. At least one Bisphosphonate Consumer's death, namely that of Sandra Wilcoxon, was caused as a direct and proximate result of being prescribed, purchased, and infused with Aredia® and/or generic Aredia (pamidronate).

B. DEFENDANTS

25. Defendant APP is a non-resident corporation with its corporate headquarters located at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

26. At all times relevant hereto, APP was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Abraxis at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States..

27. Defendant Bedford is a non-resident corporation with its corporate

headquarters located at 300 Northfield Road, Bedford, Ohio 44146.

28. At all times relevant hereto, Bedford was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Bedford at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

29. Defendant Hospira is a non-resident corporation with its corporate headquarters located at 275 North Field Drive, Lake Forest, Illinois 60045.

30. At all times relevant hereto, Hospira was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Hospira at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States.

31. Defendant Teva is a non-resident corporation with its corporate headquarters located at 19 Hughes, Irvine, California 92618.

32. At all times relevant hereto, Teva was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Teva at present or in the past, markets and distributes generic

Aredia (pamidronate) throughout the world including all fifty states in the United States.

33. Defendant Sandoz is a non-resident corporation with its corporate headquarters located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

34. At all times relevant hereto, Sandoz was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Sandoz at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States.

III. NON-PARTIES

35. Non-party Novartis is a non-resident corporation with its corporate headquarters located at 1 Health Plaza, East Hanover, New Jersey, 07936-1080. At all times relevant hereto, NPC was engaged in the business of marketing, distributing, promoting, testing, labeling and selling the drugs Aredia® and Zometa®. Novartis, at present or in the past, markets and distributes Aredia® and Zometa® throughout the world, including all fifty states in the United States.

IV. JURISDICTION AND VENUE

36. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332

(diversity jurisdiction) because the amount in controversy exceeds \$75,000 exclusive of interest and costs, and because this is an action by individual Plaintiffs who are all citizens of different states from all the Defendants. Venue is proper in this District pursuant to 28 U.S.C. §§ 1331(a) and 1331(c).

V. FACTUAL BACKGROUND

37. Aredia[®], generic Aredia (pamidronate), and Zometa[®] are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Zometa[®] is NPC's "successor" drug to Aredia[®], as Aredia[®] was the first generation version of the drug Zometa[®]. Zometa[®] is now marketed by NPC for all or almost of the uses for which it previously marketed Aredia[®]. Aredia[®], generic Aredia (pamidronate), and Zometa[®] have been approved by the United States Food and Drug Administration.

38. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia[®]); zoledronic acid or zoledronate (Zometa[®]); ibandronate (Bondronat[®]); risedronate sodium (Actonel[®]); and alendronate (Fosamax[®]). The non-nitrogenous bisphosphonates include the following: etidronate (Didronel[®]); clodronate (Bonefos[®] and Loron[®]); and tiludronate (Skelid[®]). Aredia[®], generic Aredia

(pamidronate), and Zometa® contain a nitrogen atom, whereas etidronate, clodronate, and tiludronate do not.

39. Studies and medical practices report the frequent and common occurrence of osteonecrosis of the jaw in the users of the nitrogenous bisphosphonates, including Aredia®, generic Aredia (pamidronate), and Zometa®.

40. The Defendants knew or should have known of the disease phosphorus necrosis of the jaw or “phossy jaw,” which appeared in the 1800s in persons mining white phosphorus and persons working in white phosphorus match factories. Phossy jaw had been nearly eliminated in the last century through industrial hygiene. The operation of the active ingredients in Aredia®, generic Aredia (pamidronate), and Zometa® acts and has the same effect as the phosphorus byproducts that caused “phossy jaw.” It was foreseeable that any drug with the characteristics of Aredia®, generic Aredia (pamidronate), and Zometa® would carry the risk of a “phossy jaw”-like reaction.

41. The process by which old bone is taken away and new bone is created is called “remodeling.” Aredia®, generic Aredia (pamidronate), and Zometa® were all designed specifically to affect the “remodeling” process. Medical science knew, and therefore the Defendants knew or should have known, that the jaw operates differently from other bones in the body in that it is subject to unique stresses, and

accordingly “remodels” at a far, far greater rate than other bones in the body. Medical science knew, and therefore the Defendants knew or should have known, that bisphosphonate drugs have a “site preference” for high remodeling areas, and therefore would have a heightened effect on bones that remodel at a higher rate. Despite this knowledge not one dentist, maxillofacial surgeon, or other jaw or mouth bone specialist was used or assigned to any clinical trial done by NPC for either Aredia® or Zometa®. This failure constituted a design flaw in every clinical trial and tainted all information provided to the FDA, other regulatory authorities, and peer reviewed journals. Nonetheless, despite any intention of examining the jaw or mouth and without utilization of any oral specialists in the clinical trials, NPC’s data captured at least six persons who self-reported ONJ-like symptoms in the Zometa® clinical trials. NPC failed properly to report this to the FDA as part of Novartis’s application for approval to market the drug, and further failed to report other adverse event reports to the FDA in a timely manner.

42. The Defendants knew and or should have known that bisphosphonates, including Aredia®, generic Aredia (pamidronate), and Zometa®, inhibit the activity of osteoclasts in the bone. Similarly, the Defendants knew or should have known that bisphosphonates cause changes specific to patients’

mandibles (lower jaws) and maxillae (upper jaws) and that these changes appear to be cumulative in nature.

43. The Defendants also knew or should have known that these factors can progress to jaw necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

44. On information and belief, in the year 2002 or before, NPC was notified by one physician that he had dozens of cases in which patients taking Aredia® had experienced problems so severe that they had lost portions of their jaws. Other oral surgeons during that time frame and before had been reporting such problems to NPC. On information and belief, NPC had similar information as to adverse effects caused by its drug Zometa®, which has similar properties and effects as Aredia® and is marketed by NPC as a more effective replacement for Aredia®. Nevertheless, NPC did not undertake to advise physicians, notify the consuming public or place information about the possibility of suffering osteonecrosis of the jaw on their products until September of 2004. NPC did not undertake to notify dental professionals until May of 2005. These efforts to date by NPC to provide notice are not adequate to provide the public and health care professionals with the information needed to understand the risks inherent in the use of Aredia® and Zometa®, and indeed are themselves false and misleading.

45. Shortly after NPC began selling Zometa®, reports of osteonecrosis of the jaw and other dental complications among users further exploded, indicating that Zometa® shared the class effects of the other nitrogenous bisphosphonates including Aredia® and generic Aredia (pamidronate). Despite this knowledge, NPC failed to implement further study of the risk of osteonecrosis of the jaw relative to Zometa® and Aredia®. Rather than evaluating and verifying the safety of Zometa® with respect to osteonecrosis of the jaw, NPC proposed further uses of Zometa®, notably for osteoporosis under the names Reclast® or Aclasta® or other names, and upon information and belief, urged off-label uses on medical practitioners. Indeed, hundreds of articles have been written by qualified medical professionals and institutions and published in the top medical journals in the world demonstrating that Aredia® and generic Aredia (pamidronate) causes osteonecrosis of the jaw at a significant rate, and that Zometa® causes osteonecrosis of the jaw at an even higher rate.

46. Rather than warn patients and the medical community, and despite knowledge by NPC of increased risk of osteonecrosis of the jaw in patients using Zometa®, NPC continued and continues to defend and aggressively market Zometa®, while downplaying any unfavorable findings and overstating its benefits.

This includes attempting to have it approved for use in the treatment of osteoporosis, and in seeking approval to market the drug for osteoporosis changing the name of the drug to “Reclast®” or “Aclasta®” or other names in order to conceal the link between the drug and osteonecrosis of the jaw.

47. Because of the long “half-life” of the drugs Aredia®, generic Aredia (pamidronate), and Zometa® in the body, the drug remains in the bones of persons who have been infused with it for at least many, many years or even permanently. For this reason, onset of osteonecrosis of the jaw or worsening of a patient’s condition can occur years after infusions of the drug have been discontinued. For this reason, the label indications that call for an infusion of the drug every three-four weeks in perpetuity constitute an overdose.

48. Despite knowledge of the specific risk, the Defendants have failed timely to initiate studies to further investigate risks associated with the use of Aredia®, and/or generic Aredia (pamidronate), and Zometa®.

49. Further, NPC had a duty fully to test and evaluate Aredia® and Zometa® prior to their introduction to the market, to ensure that the drugs were safe to use for their intended purpose. NPC failed to satisfy this duty.

50. Upon information and belief NPC’s Safety Reporting System (also known as “STL”) generated errors and affected the reporting of safety data to the

FDA and negatively impacted clinical trials. To date the system is obsolete and still generating inaccurate safety data that is being submitted to the FDA.

51. NPC failed properly to conduct "dosing studies" to ascertain the minimum effective quantities of the drugs Aredia® and Zometa®, and thereby to establish the proper quantities of the drugs to be administered to patients and the proper number of infusions which patients should receive. Identifying the minimum effective dosage and setting the dosage instructions accordingly are critical to avoiding the occurrence of side effects. NPC, to maximize profit, for most or all label indications specified a dosage and dosing schedule of Zometa® far above any indicated for palliative effect. This dosing schedule, for most indications, calls for an infusion of the drug every three to four weeks *forever*, without any end point or time at which the use of the drug should be discontinued. As a result of NPC's failure to instruct as to the proper dosage, upon information and belief the amount of the drug actually administered to the Bisphosphonate Consumers constituted an overdose, and contributed to the side effects and harm they suffered.

COUNT I
STRICT LIABILITY

52. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

53. The Defendants were engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, which they sold and distributed throughout the world, including all fifty states in the United States.

54. The Bisphosphonate Consumers were using Aredia® and/or generic Aredia (pamidronate) in the manner for which they were intended, or in a reasonably foreseeable manner.

55. Aredia® and/or generic Aredia (pamidronate) were expected to and did reach the Bisphosphonate Consumers without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised and otherwise distributed.

56. The Bisphosphonate Consumers were not aware of, and reasonably could not have discovered, the actual dangerous nature of Aredia® and/or generic Aredia (pamidronate).

57. Aredia® and/or generic Aredia (pamidronate) cause increased risks of osteonecrosis of the jaw upon consumption, and therefore constitute products unreasonably dangerous for normal use due to their defective design, defective manufacture, and the Defendants' misrepresentations and inadequate facts disclosed

to the Bisphosphonate Consumers and their health care providers including, *inter alia*, the actual risk of developing osteonecrosis of the jaw and the permanent, irreversible harm associated with the disease.

58. As a direct and proximate result of the Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, the Bisphosphonate Consumers have suffered osteonecrosis of the jaw, and are at an increased risk of developing other diseases and conditions.

59. The Defendants, therefore, are strictly liable to the Plaintiffs and Plaintiffs are entitled to compensatory damages. Additionally, the Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. Plaintiffs therefore are entitled to punitive damages in an amount to be proven at trial.

COUNT II
NEGLIGENCE - NEGLIGENT MANUFACTURE

60. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

61. It was the duty of the Defendants to use reasonable care in the manufacturing, creating, designing, testing, sterilizing, packaging, supplying, and

otherwise distributing Aredia® and/or generic Aredia (pamidronate).

62. Contrary to their duty, the Defendants failed: adequately and properly to test and inspect Aredia® and/or generic Aredia (pamidronate) so as to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured and sold; adequately and properly to conduct a dosing study or otherwise to test Aredia® and/or generic Aredia (pamidronate) to ascertain the minimum effective dosage and to use this information to instruct users of the drugs and/or their health care providers of the proper dosage so as to minimize the risk of development of osteonecrosis of jaw or other side effects; to utilize and/or implement a reasonably safe design in the manufacture of Aredia® and/or generic Aredia (pamidronate); to manufacture Aredia® and/or generic Aredia (pamidronate) in a reasonably safe condition appropriate for the use for which they were intended.

63. The Defendants manufactured and sold Aredia® and/or generic Aredia (pamidronate), which as constituted are and were a hazard to the Bisphosphonate Consumers' health. The Defendants' manufacture and sale of Aredia® and/or generic Aredia (pamidronate) as constituted caused the Bisphosphonate Consumers to suffer adverse side effects and disease.

64. The Defendants were otherwise careless and negligent.

65. As a direct and proximate result of the Defendants' negligent, reckless,

and careless manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, the Bisphosphonate Consumers have suffered osteonecrosis of the jaw, are at an increased risk of developing other diseases and conditions, and have suffered compensatory damages and are entitled to punitive damages in amounts to be proven at trial.

COUNT III
NEGLIGENCE – FAILURE TO WARN

66. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

67. It was the duty of the Defendants to use reasonable care in the labeling, marketing, selling, advertising, and promoting of Aredia® and/or generic Aredia (pamidronate), and to warn the Bisphosphonate Consumers and their medical providers of the true risk of osteonecrosis of the jaw and other side effects when using the Defendants' drug.

68. Contrary to its duty, the Defendants failed: adequately and properly to warn the Bisphosphonate Consumers of the risks of serious complications and bodily harm when Aredia® and/or generic Aredia (pamidronate) are used in the manner for which they were intended; adequately and properly to warn the

Bisphosphonate Consumers of the risks of diseases when Aredia® and/or generic Aredia (pamidronate) are used in a manner for which they were intended; adequately and properly to label Aredia® and/or generic Aredia (pamidronate) so as to warn the Bisphosphonate Consumers of the risks of complications and disease; and adequately and properly to label Aredia® and/or generic Aredia (pamidronate) so as to warn the Bisphosphonate Consumers of the risks of osteonecrosis of the jaw.

69. Further, the Defendants failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations. The Defendants further failed in the following respects:

- a. The labeling lacked adequate information on the use of the drugs Aredia® and/or generic Aredia (pamidronate) (21 C.F.R. Section 201.56(a) and (d));
- b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57(e));
- c. There was inadequate information for patients for the safe and effective use of the Defendants' drugs (21 C.F.R 201.57(f)(2));
- d. There was inadequate information regarding special care to be exercised by the Bisphosphonate Consumers' doctors for safe and effective use of the Defendants' drugs (21 C.F.R. 201.57(f)(1));

e. The labeling was misleading and promotional (21 C.F.R. 201.56(b)); and

f. The Defendants' acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

70. The Defendants' products Aredia® and/or generic Aredia (pamidronate) were unaccompanied by proper and adequate warnings regarding the risk of osteonecrosis of the jaw associated with the use of the Defendants' products and the scope, severity and duration of such injuries.

71. Despite the Defendants' failure to provide adequate warnings to protect users or consumers of Aredia® and/or generic Aredia (pamidronate), the Defendants nevertheless continued aggressively to market, promote, distribute, and sell the dangerously defective products.

72. As a result of the Defendants' negligence and the violations of the statutes and regulations listed above, the Bisphosphonate Consumers suffered injuries and damages as alleged herein.

73. As a direct and proximate result of the Defendants' failure to warn, the Bisphosphonate Consumers has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT IV

BREACH OF EXPRESS WARRANTY

74. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

75. The Defendants expressly warranted to the Bisphosphonate Consumers, by and through statements made by the Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Aredia® and/or generic Aredia (pamidronate) were safe, effective, fit and proper for their intended use.

76. In using Aredia® and/or generic Aredia (pamidronate), the Bisphosphonate Consumers and their health care providers relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

77. As a direct and proximate result of the Defendants' breaches of warranties, the Bisphosphonate Consumers have developed osteonecrosis of the jaw, are at risk of developing other diseases, and have suffered compensatory damages and are entitled to punitive damages in amounts to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY

78. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

79. Prior to the time that Aredia® and/or generic Aredia (pamidronate) were used by the Bisphosphonate Consumers, the Defendants impliedly warranted to the Bisphosphonate Consumers that Aredia® and/or generic Aredia (pamidronate) were of merchantable quality and safe and fit for the use for which they were intended. The Bisphosphonate Consumers are unskilled in the research, design and manufacture of Aredia® and/or generic Aredia (pamidronate), and reasonably relied on the skill, judgment and implied warranty of the Defendants in using Aredia® and/or generic Aredia (pamidronate).

80. Aredia® and/or generic Aredia (pamidronate) were neither safe for their intended use nor of merchantable quality, as warranted by the Defendants, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

81. As a direct and proximate result of the Defendants' breaches of warranties, the Bisphosphonate Consumers have developed osteonecrosis of the jaw, are at risk of developing other diseases, and have suffered compensatory damages and are entitled to punitive damages in amounts to be proven at trial.

COUNT VI
LOSS OF CONSORTIUM

82. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

83. As a proximate cause of the Defendants' wrongful conduct resulting in the injuries the Bisphosphonate Consumers have suffered as described herein, Johnny Rodriguez, Allen Kruszka, Michael Lambertson, Robert Berry, Martha Warchol, Gary Venne, Luther Compton, and Ted Wilcoxen (collectively, the "Bisphosphonate Consumers Spouses") lost the spousal consortium of the Bisphosphonate Consumers. The Bisphosphonate Consumers Spouses will likely continue to lose the Bisphosphonate Consumer's consortium in the future due to the Defendants' wrongful conduct.

84. Accordingly, Bisphosphonate Consumers Spouses have suffered compensatory damages in an amount to be proven at trial. Bisphosphonate Consumers Spouses hereby aver that the acts committed by Defendants, and their willful and wanton acts and legal malice constitute aggravating factors which support an award of punitive damages.

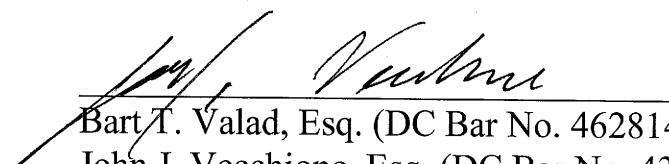
WHEREFORE, Plaintiffs pray that this honorable Court enter judgment against Defendants, and in favor of the Plaintiffs, and to award the following relief:

- a. Award the Bisphosphonate Consumers all damages allowed by law to compensate them for their physical injury, pain, suffering, emotional distress, mental anguish, physical disability and physical disfigurement and other losses which they have endured;
- b. Award the Bisphosphonate Consumers damages equal to the amount of their medical and health care costs and expenses incurred to present and in the future;
- c. Award the Bisphosphonate Consumers damages in an amount sufficient to compensate them for the likely future deterioration of their medical condition as a result of the harm they have suffered from use of the Defendants' products;
- d. Award the Bisphosphonate Consumers Spouses damages for their loss of companionship and consortium with their spouses;
- e. Award Plaintiffs damages equal to any amount of lost wages and earnings;
- f. Award Plaintiffs punitive/exemplary damages to the extent necessary and appropriate to punish and deter the conduct complained of herein;
- g. Award Plaintiffs attorneys' fees and costs, plus interest, as allowed by law; and
- h. Award Plaintiffs such other and further legal and equitable relief as this honorable Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury of this action.

VALAD & VECCHIONE, PLLC


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